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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,813	08/02/2001	Saverio Carl Falco	BB-1430	6600
7590 04/20/2004				
Thomas M Rizzo E I du Pont de Nemours & Company Legal Patents Wilmington, DE 19898			EXAMINER BUI, PHUONG T	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/890,813

Applicant(s)

FALCO ET AL.

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-48 is/are pending in the application.
- 4a) Of the above claim(s) 42-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-31 and 34-41 is/are rejected.
- 7) ☒ Claim(s) 32-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/11/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed February 25, 2004. In view of newly added claims, the claims are further restricted as follows under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 28-41, drawn to a polynucleotide, method of transforming a cell, and method of producing a transgenic plant.

Group II, claim(s) 42-48, drawn to a plant having an altered level of an amino acid.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the plant of group I does not necessarily express aspartate kinase and does not necessarily have an altered level of an amino acid.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Group I is elected by original presentation. In Applicant's restriction election, Applicant elected Group I and SEQ ID NO:6 with traverse, stating that SEQ ID NO:6 and 8 are 95.7% identical to each other. Applicant's traversal is unpersuasive because sequence searches are individually submitted by SEQ ID No. identifier, and thus a

search of SEQ ID NO:6 would not be co-extensive with a search of SEQ ID NO:8. Accordingly, claims 28-41 and SEQ ID NO:5 encoding SEQ ID NO:6 are examined in the instant application. Claims 42-48 are nonelected. This restriction is made final. It is suggested that Applicant amend the claims as appropriate to remove nonelected inventions.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:5 and its corresponding amino acid sequence SEQ ID NO:6, it is unclear where the open reading frame of SEQ ID NO:5 begins and ends. Clarification is required.

Information Disclosure Statement

3. A dated and initialed copy of Applicant's IDS is attached to the instant Office action.

Specification

4. The specification is objected to because of the following: 1) to claim priority benefit, Applicant is required to also include the PCT application information, since the provisional application was filed more than twelve months prior to the filing of the instant application (see MPEP 201.11). 2) Moreover, current US patent policy does not permit the use of hyperlinks in the specification. Such links are directed to an Internet site, the contents of which are subject to change without notice. Therefore, the potential for inclusion of new matter would be a constant problem. See pages 11 and 26, for example. 3) Additionally, the amino acid sequences on pages 35-36 must be identified

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by a SEQ ID NO. identifier in the specification, either by its own SEQ ID NO. or as positions x to y of a SEQ ID NO. (see 37 CFR 1.821 (d)) Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Before the polypeptide can be isolated, it must be expressed. Correction is required.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 28-31 and 34-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5 or a sequence encoding SEQ ID NO:6, does not reasonably provide enablement for sequences having less than 100% sequence identity with these sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining enzymatic activity. Applicant provided no working examples or

further guidance as to which region(s) of SEQ ID NO:5 or 6 are conserved domains necessary for protein activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated. Accordingly, the claimed invention is not enabled.

9. Claims 28-31 and 34-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims reciting 80-95% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass aspartate kinases from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:5 isolated from *Zea mays*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and aspartate kinases from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See

Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

10. Claims 32-33 are objected to as reciting nonelected inventions but would be allowable if amended to remove the nonelected inventions. SEQ ID NO:5 and a nucleotide sequence encoding SEQ ID NO:6 are free of the prior art. It is understood by the Office the Clustal alignment method recited in the claims uses the default parameters set forth on page 11, lines 17-19 of the specification. The closest prior art teaches a sequence isolated from *Glycine max* having 66.4% sequence identity with SEQ ID NO:6 (Table 5, p. 28; and Esau et al., National Center for Biotechnology Information General Identifier No: 5305740, 6-24-99 (Applicant's IDS)).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

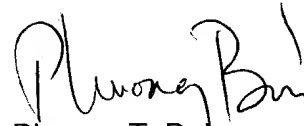
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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Phuong T. Bui". The signature is stylized with a large, looped "P" and a long, sweeping "B".

Phuong T. Bui
Primary Examiner
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4/17/04